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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Gregory B. Wilson and R. Riley Shuler
U.S. Serial No.	:	09/776,010 Examiner: B. Q. Li
Filed	:	February 2, 2001 Group Art Unit: 1648
For	:	HUMAN HERPESVIRUS 6A AND 6B TRANSFER FACTORS FOR THE TREATMENT OF CHRONIC FATIGUE SYNDROME AND MULTIPLE SCLEROSIS

1185 Avenue of the Americas
New York, New York 10036
April 17, 2003

Assistant Commissioner for Patents
Washington, D.C. 20231

COMMUNICATION IN RESPONSE TO DECEMBER 17, 2002 OFFICE ACTION AND PETITION FOR THREE-MONTH EXTENSION OF TIME

This Communication is submitted in response to a December 17, 2002 Office Action issued in connection with the above-identified application. A response to the December 17, 2002 Office Action was due January 17, 2003. Applicants hereby petition for a three-month extension of time to respond. The fee for a small entity for a two month extension of time is FOUR HUNDRED AND SIXTY FIVE DOLLARS ($465.00) and a check for this amount is enclosed. Small entity status has previously been established. With a three-month extension of time a response is now due April 17, 2003. Accordingly, this response is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

In the December 17, 2002 Office Action the Examiner stated that restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 32, 34, 36, 38, drawn to a composition comprising a cell-free fluid secreted from a mammary gland of a human herpesvirus-6A infected lactating mammal, classified in class 424, subclass 439.

II. Claims 33, 35, 37 and 39, drawn to a composition comprising a cell-free fluid secreted from a mammary gland of a human herpesvirus-6B infected lactating mammal, classified in class 424, subclass 189.1.

III. Claims 40, 42 and 43, drawn to a method for treating chronic fatigue, classified in class 424, subclass 93.1.

IV. Claims 41 and 44-45, drawn to a method for treating multiple sclerosis, classified in class 424, subclass 9.1.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that inventions of group I and II are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The Examiner further stated that in the instant case the different inventions of Groups I and II are directed to the products isolated from different sources, one is from a mammal infected with HSV-6A and another is from the mammal infected from HSV-6B.

The Examiner stated that inventions of group III and IV are unrelated. The Examiner stated that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects (MPEP §806.04, MPEP §808.01). The Examiner further stated that in the instant case the different inventions of Groups III and IV are directed to different methods, e.g. the method of Group III is used for treating chronic fatigue syndrome, whereas the method of Group IV is used for treating multiple sclerosis.

The Examiner stated that inventions Group I and Group III are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner stated that in the instant case the process for using the product as claimed can be practiced with another material different product, such as hormone.

The Examiner stated that because these inventions are distinct for the reasons given above, restriction for examination purpose as indicated is proper, and that applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR §1.143).

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Examiner's Group III, drawn to a method for treating chronic fatigue syndrome.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two

or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn in view of the fact that the claims of Groups I-IV are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect...". The claims of Group I-II are related in that they are drawn to similar compounds, compositions, and methods of use. All of the methods relate to repairing ischemic damaged tissue in a subject.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I-IV would necessarily identify art

for the other Groups. Since there is no serious burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits. More specifically, applicants maintain that a search of prior art with regard to Group III or IV would necessarily identify art for the Group I or II respectively.

Applicants maintain that claims 32-45 define a single inventive concept. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 32-45 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the $465.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Communication. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

4/17/03
John P. White Date
Reg. No. 28,678